Message Text

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ACTION EUR-12

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SUBJECT: EC PHARMACEUTICAL HARMONIZATION

REFS: A. EC BRUSSELS 1255
B. EC BRUSSELS 431
C. EC BRUSSELS 10151, 1974

BEGIN UNCLASSIFIED

1. SUMMARY: BY APPROVING THE SECOND AND THIRD DRAFT DIRECTIVES ON EC PHARMACEUTICAL HARMONIZATION, THE FEBRUARY 10-11 EC COUNCIL HAS PUT THE FINAL TOUCHES ON A SYSTEM WHICH COMES VERY CLOSE TO ALLOWING THE FREE CIRCULATION OF PHARMACEUTICALS IN THE COMMUNITY. COMMISSION SOURCES CONFIRMED OUR BELIEF THAT THE APPLICATION OF THE DRAFT DIRECTIVES SHOULD SIMPLIFY THE SALE OF US PHARMACEUTICAL PRODUCTS IN THE MEMBER STATES. END SUMMARY.

2. AS REPORTED IN REFTEL A, PARA 7, THE EC COUNCIL AT ITS MEETING ON FEBRUARY 10-11, AGREED TO THE SECOND DRAFT EC COUNCIL DIRECTIVE ON PHARMACEUTICAL
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PRODUCTS, ALTHOUGH FORMAL COUNCIL APPROVAL MUST

AWAIT FORMATION OF A DANISH GOVERNMENT. THE FINAL
AGREED TEXT IS VERY CLOSE TO THAT WHICH WAS
TRANSMITTED WITH A TRANSMITTAL SLIP TO EUR/RPE
ON DEC. 17, 1974.

3. THE EC COUNCIL ALSO AGREED AT THE FEBRUARY MEETING
ON THE THIRD DRAFT EC COUNCIL DIRECTIVE ON
PHARMACEUTICALS WHICH IS THE DIRECTIVE DEALING
WITH THE HARMONIZATION OF "NORMS AND PROTOCOLOS"
CONCERNING STANDARDS AND PROCEDURES IN PHARMACEUTICAL
TESTING. THIS DIRECTIVE IMPOSES ON THE MEMBER STATES
THE RESPONSIBILITY TO ASSURE THAT THE INFORMATION
PRESENTED BY PHARMACEUTICAL COMPANIES SEEKING
MARKETING LICENSES FOR AGIVEN PRODUCT IS PRESENTED
IN A DETAILED AND STANDARDIZED MANNER AND TO ASSURE
THAT THE COMPETENT AUTHORITIES IN THE MEMBER STATES
APPLY THE TESTING CRITERIA CONTAINED IN THE ANNEXES
TO THE DIRECTIVE. (A COPY OF THE LATEST DRAFT OF
THE THIRD DRAFT DIRECTIVE, WHICH IS ESSENTIALLY AS
IT WILL APPEAR IN FINAL FORM, HAS BEEN TRANSMITTED
TO EUR/RPE, ATTENTION R. HARDING).

4. BELGIUM HAS BEEN CONCERNED THAT THE NEW SYSTEM
WOULD RESULT IN FLODDING THE BELGIAN MARKET WITH
PRODUCTS WHICH DUPLICATE EACH OTHER. AN ADVISORY
COMMITTEE WILL BE ESTABLISHED, COMPOSED OF MEMBER
STATE EXPERTS, TO ASSIST THE COMMISSION IN
DETERMINING WHAT MIGHT BE DONE IF BELGIAN FEARS
MATERIALIZE. IN ANY CASE, THE COMMISSION WILL TAKE A FRESH
LOOK AT THE FIRST DIRECTIVE ON PHARMACEUTICALS DEALING
WITH THE CRITERIA FOR REFUSING MARKETING LICENSES, WHICH
WAS PASSED BY THE COUNCIL IN 1965 (SEE OFFICIAL
JOURNALS OF THE EUROPEAN COMMUNITIES OF FEBEURARY 9, 1965 AND
AUGUST 5, 1966. THE COMMERCE CLEARING HOUSE, COMMON MARKET REPORTS
ART. 100, PARAGRAPH 3401 HAS THE TEXT AND AN EXPLANATION OF THE
FIRST DIRECTIVE). ALTHOUGH THERE MAY EVENTUALLY BE SOME REVISION
OF THE FIRST DIRECTIVE, THE THREE AGREED UPON DIRECTIVES NOW
ESTABLISH A SYSTEM FOR ALMOST COMPLETELY FREE CIRCULATION OF
PHARMACEUTICAL PRODUCTS THROUGHOUT THE COMMUNITY
(MEMBER STATES STILL CAN REFUSE MARKETING LICENSES EVEN IF
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ALREADY OBTAINED IN ANOTHER MEMBER STATE BUT IT IS MUCH MORE
DIFFICULT FOR THEM TO DO SO).
THE MEMBER STATES WILL HAVE TO INTRODUCE WITHIN 18 MONTHS OF
PUBLICATION OF THE DIRECTIVES IN THE OFFICIALS JOURNAL, THE
INTERNAL MEASURES THAT WILL BE NEEDED TO MAKE THE DIRECTIVES
APPLICABLE.

5. A COMMISSION OFFICIAL IN THE DIRECTORATE GENERAL FOR THE

INTERNAL MARKET (DUPRAT), DEALING WITH THE
DRAFT DIRECTIVES, CONFIRMED OUR READING OF THE SECOND DRAFT
DIRECTIVE THAT THE NEW SYSTEM WOULD MAKE IT EASIER FOR PHAR-
MACEUTICAL IMPORTS FROM THIRD COUNTRIES (SEE REFTEL C, PARA 4).
ONCE A THIRD COUNTRY MANUFACTURER HAS RECEIVED A MANUFACTURING AND
MARKETING AUTHORIZATION FROM ONE MEMBER STATE (ART. 14) AND THE
PRODUCT SATISFIES THAT STATE'S BATCH TESTING REQUIREMENTS
REGARDING THE PRODUCT (ART. 20, THE PRODUCT STANDS ON THE SAME
FOOTING AS MEMBER STATE PRODUCTS REGARDING MARKETING LICENSES
IN OTHER MEMBER STATES AND ACCESS TO THE FACILITIES
OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
(CHAPTER III). END UNCLASSIFIED.

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6. COMMENT: WE ASKED DUPRAT WHAT ACCOUNTED FOR THE
BREAKING OF THE IMPASSE ON THE SECOND DRAFT DIRECTIVE
AS IT HAS BEEN BEFORE THE COUNCIL FOR OVER TEN
YEARS. HE GAVE A GREAT DEAL OF CREDIT TO FRENCH
MINISTER OF HEALTH SIMONE VEIL, WHO TURNED HER
MINISTRY AROUND ON IMPORTANT ISSUES AND RESISTED
STRONG PRESSURE FROM POWERFUL FRENCH INTERESTS.
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